

Peer Review and Public Comment Plan for “Laboratory Recommendations for Syphilis Testing in the United States”

Title: “Laboratory Recommendations for Syphilis Testing in the United States”

Subject of Planned Report: This document summarizes the evidence informing best practices for the laboratory detection of infections caused by *T. pallidum* in the United States.

Purpose of Planned Report: The Centers for Disease Control and Prevention (CDC) provides evidence-based recommendations for the management of infectious diseases from laboratory testing to treatment. Syphilis is caused by the bacteria *T. pallidum* and supportive diagnosis has been traditionally relied on serologic measurements with decades-old tests. New serologic tests and direct bacterial detection tests have been introduced into the United States without a comprehensive review as to how these tests should be used to enhance the diagnosis of syphilis to reduce morbidity and transmission. The target audience for these recommendations includes laboratory directors and laboratory staff that establish standard operating procedures for collecting and processing specimens and interpret test results for laboratory reporting. They may also benefit clinicians who must choose among multiple tests and use those results along with medical history, clinical findings and epidemiologic data to inform the clinical diagnosis of syphilis.

Type of Dissemination: Influential Scientific Information (ISI)

Timing of Review (including deferrals): February-March 2022

Type of Peer Review (panel, individual or alternative procedure): Individual

Opportunities for the Public to Comment (how and when): A notice inviting the public to comment will be posted in the Federal Register with a link to the draft recommendations. [add details regarding the open period for comment and public access to comments/responses]. The draft recommendations will be made available to key stakeholders such as the Association of Public Health Laboratories, American Society for Microbiology, Centers for Medicaid Services, and Food and Drug Administration for comment. All materials will be available for review.

Peer Reviewers Provided with Public Comments before the Review: No

Anticipated Number of Reviewers: 4

Primary Disciplines or Expertise: Clinical laboratory diagnostics, clinical care of patients infected with sexually transmitted diseases, regulatory assessment of tests marketed for clinical diagnostics in the United States.

Reviewers Selected by (agency or designated outside organization): Centers for Disease Control and Prevention (CDC)

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: We request your review of the body of literature used to develop “Laboratory Recommendations for Syphilis Testing in the United States”. As you review the Background, Methods, and Results sections, we would appreciate your thoughts as to whether any key studies have been left out or, in your opinion, misinterpreted as well as comments on the appropriateness of the conclusions. Above all, we are interested in your thoughts about the determinations regarding the quality of the evidence and the strength of the recommendations that were drawn. The questions below will serve as a template to collect and organize your responses. Once you complete your review, please send the review back to the CDC. After the Division of STD Prevention (DSTDP) reviews your comments, they will be posted without attribution along with our responses on the DSTDP webpage at a later date.

Template of specific questions:

1. Are there omissions of information or key studies that are critical for the intended audience of clinical laboratory scientists, clinicians, and community health workers? If so, what should be included?
2. Have we included inappropriate information? If so, what should be removed?
3. Does the current scientific understanding of the biology of *T. pallidum* align with the terms “nontreponemal tests” and “treponemal tests” as discussed under the section Syphilis Serologic Laboratory Testing Terminology? Should new terms for nontreponemal tests and treponemal tests be adopted if scientifically appropriate? Would updating these terms add to confusion in the literature? Do you foresee any regulatory implications regarding product insert literature if new terms are proposed? Please explain.
4. Are the recommendations appropriately drawn from the evidence presented? Please explain.
5. Is this document clear and comprehensible? If not, which sections should be revised?
6. Are the recommendations practical and achievable? For example, are resources available for laboratories interested in establishing darkfield microscopy? If not, do you have any suggestions regarding capacity building to ensure the recommendations are practical and achievable.
7. Other comments you might have?

Selected Peer Reviewers

Name	Academic and Professional Credentials	Current Affiliation	Areas of Interest
Megan Crumpler	Ph.D., Microbiology and Immunology, Virginia Commonwealth University School of Medicine, Richmond, Virginia. Board Certification: High Complexity Clinical Laboratory Director, American Board of Bioanalysis.	Laboratory Director at Orange County Public Health Laboratory, Santa Ana, CA	Public Health Laboratory Director

Sheila Lukehart	Ph.D., University of California, Los Angeles, CA	Professor Global Health, Associate Dean in the School of Medicine, University of Washington, Seattle, WA.	Sexually transmitted infections with an emphasis on syphilis, Pathobiology, and drug/vaccine development
Beth Marlow	Ph.D. Microbiology and molecular biology. University of Arizona, Tucson, AZ Board Certification: American Board of Medical Microbiology	Senior Scientific Director, Infectious Diseases at Quest Diagnostics, Orange County, CA	Clinical Laboratory Director, previous Global Director Medical Affairs, Microbiology, Roche Diagnostics
Arlene Seña	MD, University of North Carolina, Chapel Hill, NC MPH, University of North Carolina, Chapel Hill, NC Board Certifications: Internal Medicine Infectious Diseases	Professor of Medicine, Division of Infectious Diseases, University of North Carolina, Chapel Hill, NC	Sexually transmitted infections (STIs), with a particular interest in diagnostics and therapeutic regimens for syphilis.

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